Surgery, PACU and Anesthesia Standards:
CMS HOSPITAL CONDITIONS OF PARTICIPATION (COPS) 2014

TELNET 2904  May 6, 2014  10-11:30 am EDT

Speaker

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Author of Book on the CMS Anesthesia Standards

Cracking the Code
Understanding the CMS Hospital CoP Standards on Anesthesia

You Don’t Want One of These
The Conditions of Participation (CoPs)

- Many revisions in past to respiratory and rehab orders, visitation, IV medication blood, and opioids, anesthesia, pharmacy, timing of medications, confidentiality & privacy, PI, luer misconnections, discharge planning and equipment maintenance

- Manual updated February 14, 2014

- First regulations are published in the Federal Register then CMS publishes the Interpretive Guidelines and some have survey procedures

- Hospitals should check this website once a month for changes


CMS Survey and Certification Website

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

Click on Policy & Memos
### CMS Survey Memos Issued

- IV, Medications, Opioid March 14, 2014
- Emergency Preparedness Checklist Feb 28, 2014
- Emergency Preparedness Draft Changes Jan 3, 2014
- Hospital Equipment Maintenance Dec 20, 2013
- Privacy and confidentiality memo on March 2, 2012
- Complaint manual updated April 19, 2013
- Access to hospital deficiency data March 22, 2013
- Use of insulin pens issue May 18, 2012
- Discharge planning rewritten May 17, 2013
- Reporting to internal PI March 15, 2013
- Luer Misconnections March 8, 2013
Subscribe to the Federal Register

### Location of CMS Hospital CoP Manual

**Medicare State Operations Manual**

**Appendix**

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the red button in the ‘Download’ column to see any available file in PDF.
- To return to this page after opening a PDF file on your desktop, use the browser “back” button. This is because closing the file usually will also close most browsers.


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<td>AA</td>
<td>Psychiatric Hospitals</td>
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June 15, 2012 CMS issues a 7 page memo on safe injection practices

- Discusses the safe use of single dose medication to prevent healthcare associated infections (HAI)
- Notes new exception which is important especially in medications shortages
- General rule is that single dose vial (SDV) can only be used on one patient
- Will allow SDV to be used on multiple patients if prepared by pharmacist under laminar hood following USP 797 guidelines

**Memorandum Summary**

- Under certain conditions, it is permissible to repack single dose vials or single use vials (collectively referred to in this memorandum as “SDVs”) into smaller doses, each intended for a single patient. The United States Pharmacopoeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§ 501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, Pharmaceutical Compounding - Sterile Preparations (USP 797-). Under USP 797-, healthcare facilities may repack SDVs into smaller doses, each intended for use with one patient. Among other things, these standards currently require that:
  - The facility doing the repackaging must use qualified, trained personnel to do so. Under International Organization for Standardization (ISO) Class 5 or air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
  - All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP 797-; by the licensed healthcare professional supervising the repackaging process.
  - Administration doses from one SDV to multiple patients without adherence to USP 797-
CMS Memo on Safe Injection Practices

- All entries into a SDV for purposes of repackaging must be completed with 6 hours of the initial puncture in pharmacy following USP guidelines
- Only exception of when SDV can be used on multiple patients
- Otherwise using a single dose vial on multiple patients is a violation of CDC standards
- CMS will cite hospital under the hospital CoP infection control standards since must provide sanitary environment
  - Also includes ASCs, hospice, LTC, home health, CAH, dialysis, etc.

CMS Memo on Safe Injection Practices

- Bottom line is you can not use a single dose vial on multiple patients
- CMS requires hospitals to follow nationally recognized standards of care like the CDC guidelines
- SDV typically lack an antimicrobial preservative
- Once the vial is entered the contents can support the growth of microorganisms
- The vials must have a beyond use date (BUD) and storage conditions on the label
CMS Memo on Safe Injection Practices

- Make sure pharmacist has a copy of this memo
- If medication is repackaged under an arrangement with an off site vendor or compounding facility ask for evidence they have adhered to 797 standards
- ASHP Foundation has a tool for assessing contractors who provide sterile products
- Go to www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx
- Click on starting using sterile products outsourcing tool now
CMS Hospital Worksheets Third Revision

- October 14, 2011 CMS issues a 137 page memo in the survey and certification section
- Addresses discharge planning, infection control, and QAPI
- It was pilot tested in hospitals in 11 states and on May 18, 2012 CMS published a second revised edition
  - Piloted test each of the 3 in every state over summer 2012
- November 9, 2012 CMS issued the third revised worksheet which is now 88 pages
- Final worksheet on discharge planning completed for 2014

Third Revised Worksheets

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
4200 Chaifetz Place, Suite 1150
Cincinnati, OH 45226
Attention: CMS Hospital

Center for Clinical Standards and Quality Survey & Certification Group

DATE: November 9, 2012
TO: State Survey Agency Directors
FROM: Director Survey & Certification Group
SUBJECT: Patient Safety Initiative FY 2013 Pilot Phase — Revised Draft Surveyor Worksheets

Memorandum Summary

- Patient Safety Initiative: The Center for Medicare & Medicaid Services (CMS) is continuing to work with surveyors to help ensure compliance with three hospital conditions of participation: Council on Survey Certification, Infection Control, and Discharge Planning. We are focusing on compliance with three CMS categories of hospital-acquired conditions (HACs), including healthcare-associated infections (HAIs), and preventable readmissions.
- Draft Worksheets Made Public: Via this memorandum we are making the revised draft worksheets publicly available. As was the case previously, there may be additional revisions to the worksheets at the end of FY 2013.

Patient Safety Initiative: Pilot Phase

The Survey & Certification Group (SCG) Patient Safety Initiative is continuing to pilot new three hospital conditions of participation in the 2013 survey year to help ensure surveyor compliance with the hospital conditions of participation (CoPs) for Council on Survey Certification, Infection Control, and Discharge Planning. In SCG-12-01, released October 14, 2011 and in SCG-12-02 released May 15, 2012, we made available to the public region of the initial and revised versions of the worksheets. These worksheets were used during the pre-test and pilot phases of the SCG initiative, from September 2011 through September 2012.
CMS Hospital Worksheets

- However, some of the questions asked might not be apparent from a reading of the CoPs
  - A worksheet is a good communication device
  - It will help clearly communicate to hospitals what is going to be asked in these 3 important areas
  - Anesthesia can **not** give single dose medications to more than one person unless prepared in pharmacy
  - One needle, one syringe every time
  - Hospitals might want to consider putting together a team to review the 3 worksheets and complete the form in advance as a self assessment

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Section 2. B Injection Practices and Sharps Safety (Medications, Saline, Other Infusates)

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<th>Manner of Assessment Code (check all that apply &amp; Surveys/Notes)</th>
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<td>Yes</td>
<td>1 2 3 N/A</td>
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<td>2.1.1.2.2.: Needles are used for only one patient.</td>
<td>Yes</td>
<td>1 2 3 N/A</td>
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<tr>
<td>2.1.1.3.1.: Syringes are used for only one patient. (This includes manufactured and unfilled syringes and needles)</td>
<td>Yes</td>
<td>1 2 3 N/A</td>
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Injection Practices & Sharps Safety 2 B

- Injections prepared using aseptic technique in area cleaned and free of blood and bodily fluids
- Is rubber septum disinfected with alcohol before piercing?
- Are single dose vials, IV bags, IV tubing and connectors used on only one patient?
- Are multidose vials dated when opened and discarded in 28 days unless shorter time by manufacturer?
- Make sure expiration date is clear as per P&P
- If multidose vial found in patient care area must be used on only one patient

Safe Injection Practices Patient Safety Brief

By: Sue Dill Calloway RN MSN JD CPHRM
Ruth Camico PhD RN FSHEA CIC

July 2012

The Centers for Disease Control and Prevention (CDC) says there are 1.7 million healthcare-associated infections in the US every year. Of these, it is estimated that about 99,000 deaths occur as a result. Infection prevention...
Injection Practices & Sharps Safety

- Are all sharps disposed of in resistant sharps container?
- Are sharp containers replaced when fill line is reached?
- Are sharps disposed of in accordance with state medical waste rules
- Hospitals should have a system in place where someone has the responsibility to check these and ensure they are replaced when they are full

Unsafe Injection Practices and Disease Transmission

1. A clean syringe and needle are used to draw the solution from a new vial.
2. The needle is then administered to a patient who has been previously infected with Hepatitis C virus (HCV). Blood from the needle contaminates the syringe with HCV.
3. The needle is replaced, but the syringe is reused to draw additional solution from the same vial, contaminating the vial with HCV.
4. A clean needle and syringe are used for another patient, but the contaminated vial is reused. So, both patients are at risk for infection.

Source: www.southernnevadahealthdistrict.org
Not All Vials Are Created Equal

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SINGLE-DOSE OR MULTI-DOSE?

Not all vials are created equal.

Dozens of recent outbreaks have been associated with reuse of single-dose vials and misuse of multiple-dose vials. As a result of these incidents, patients have suffered significant harms, including death. CDC and the One & Only Campaign urge healthcare providers to recognize the differences between single-dose and multiple-dose vials and to understand appropriate use of each container type. This information can literally save a life.

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Access to Hospital Complaint Data

- CMS issued Survey and Certification memo on March 22, 2013 regarding access to hospital complaint data
- Includes acute care and CAH hospitals
  - Does not include the plan of correction but can request
  - Questions to bettercare@cms.hhs.com
- This is the CMS 2567 deficiency data and lists the tag numbers
- Will update quarterly
  - Available under downloads on the hospital website at www.cms.gov
Access to Hospital Complaint Data

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop U3-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

DATE: March 22, 2013
TO: State Survey Agency Directors
FROM: Director, Survey and Certification Group

Memorandum Summary

- **Survey Findings Posted on [Website]**: In July 2012, the Centers for Medicare & Medicaid Services (CMS) began posting redacted Statements of Deficiencies (CMS-2567) for skilled nursing facilities and nursing facilities on Nursing Home Company. In March 2013, CMS began posting CMS-2567s for short-term acute care hospitals and critical access hospitals (CAHs) for surveys based on complaints investigations. This memorandum describes the contents and location of these files.

Background – Nursing Home Survey Findings

In July 2012, CMS began posting redacted statements of deficiencies, derived from the Texas

### Anesthesia Deficiencies

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<td>Organization of Anesthesia</td>
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Surgical Services 940

- Standard: If provide surgical services, which is optional, service must be well organized
- If outpatient surgery, must be consistent in quality with inpatient care
- Must follow acceptable standards of practice, AMA, ACOS, APIC, AORN, ASA, or ASPAN
- Must be integrated into hospital wide QAPI
- Will inspect all OR rooms
- Access to OR and PACU must be limited to authorized personnel
AORN Perioperative Standards

Perioperative Standards and Recommended Practices

The 2014 Edition is a Must-Have for All Perioperative Professionals

Perioperative managers, educators, and registered nurses alike will find the updates provided in the 2014 edition of Perioperative Standards and Recommended Practices -- especially those who work in an ambulatory setting. An essential resource for both patient and worker safety where invasive procedures are performed, this new edition features:

1. Four new evidence-rated recommended practices (eight total that are evidence-rated)
2. A new evidence rating model tailored for the scope of ASC care
3. Seven ambulatory supplements to recommended practices -- customized content for ASCs
4. An easy-to-navigate layout with expanded and reorganized tables to help you find the information you need faster.

PREVIEW Perioperative Standards and Recommended Practices, 2014 Edition

New, evidence-rated Recommended Practices in 2014:
- Care of Patients Undergoing Perioperative Tumescence-assisted Procedures
- Environmental Cleaning
- Selection and Use of Packaging Systems for Sterilization
- Infection Safety

Ambulatory supplements are available for:
Surgical Services 940

- Conform to aseptic and sterile technique
- Appropriate cleaning between cases
- Room is suitable for kind of surgery performed
- Equipment available for rapid and routine sterilization which is called immediate use sterilization
- And it is monitored, inspected and maintained by biomed program
- Temperature and humidity controlled
- ACS and AORN have P&P on many of these

CMS Memo April 19, 2013

- CMS issues memo related to the relative humidity (RH)
- AORN use to say temperature maintained between 68-73 degrees and humidity between 30-60% in OR, PACU, cath lab, endoscopy rooms and instrument processing areas
- CMS says if no state law can write policy or procedure or process to implement the waiver
- Waiver allows RH between 20-60%
- In anesthetizing locations- see definition in memo
Humidity in Anesthetizing Areas

Organization and Staffing 941

- **Standard:** The organization of surgical services must be appropriate to the scope of services offered
- **Must have the appropriate equipment**
- **Must have the appropriate types and numbers of qualified personnel to furnish surgical services**
  - Department director, scrub nurse, circulator, etc.
- **The surveyor is to review the organizational chart to indicate lines of authority and delegation**
Surgery  OR Director 942-944

- Standard: OR must be supervised by experienced RN or doctor (MD/DO)
- Must have specialized training in surgery and management of surgical service operation
- Will review job description
- LPN’s and OR techs can serve as scrub nurses under supervision of RN
- Qualified RN may perform circulating duties in OR
- LPN or surgery tech may assist in circulating duties if allowed by state law & under supervision of RN who is immediately available

Surgery  942-944

- Circulating nurse must be a RN
- LPN or surgical technologist can assist the RN in carrying out circulating duties
  - As allowed by state law
- Circulating RN must be in the operating suite and available to immediately and physically respond in emergencies
- Can not be outside the department or engaged in other activities to prevent immediate intervention
- Hospital must have P&P on this
Surgical Privileges

- Surgical privileges must be delineated for all practitioners performing surgery, in accordance with competence of each practitioner.
- Surgery service must maintain roster specifying the surgical privilege.
- Privileges must be reviewed every two years.
- Current list of surgeons suspended must also be retained.
  - Discussed in the earlier sections.

Surgical Privileges

- MS bylaws must have criteria for determining privileges.
- Surgical privileges are granted in accordance with the competence of each.
- MS appraisal procedure must evaluate each practitioner’s training, education, experience, and demonstrated competence.
- As established by the QAPI program, credentialing, adherence to hospital P&P, and laws.
Surgical Privileges 945

- Must specify for each practitioner that performs surgical tasks including MD, DO, dentists, oral surgeon, podiatrists
- RNFA, NP, surgical PA, surgical tech, et. al.
- Must be based on compliance with what they are allowed to do under state law
- If task requires it to be under supervision of MD/DO this means supervising doctor is present in the same room working with the patient

Surgery Policies 951

- Aseptic and sterile surveillance and practice, including scrub technique
- Identify infected and non-infected cases
- Housekeeping requirements/procedures
- Patient care requirements
  - pre-op work area
  - patient consents and releases
  - safety practices
  - patient identification process and clinical procedures
Surgery Policies 951

- Duties of scrub and circulating nurses
- Safety practices
- Surgical counts
- Scheduling of patients for surgery
- Personnel policies in OR
- Resuscitative techniques
- DNR status
- Care of surgical specimens

Surgery Policies 951

- Malignant hyperthermia
- Protocols for all surgical procedures
- Sterilization and disinfection procedures
- Acceptable OR attire
  - AORN has guidelines on this and says all scrubs must be laundered by the hospital
- Handling infectious and biomedical waste
- Outpatient surgery post op planning
Preventing OR Fires 951

- Read detailed section on use of alcohol based skin prep and how to prevent an OR fire
- AORN has toolkit on preventing OR fires and detailed policy on flammable prep in the OR and how to prevent fires
- Special precautions developed by NFPA and incorporated into NPSG by TJC
- ASA has good document on preventing fires in the OR
- Pa Patient Safety Authority has great recommendations

Fire Safety Video

www.apsf.org/resources_video.php
APSF Fire Prevention Algorithm Mar 2013

**Fire Prevention Algorithm**

1. **Is patient at risk for surgical fire?**
   - *Procedures involving the head, neck and upper chest/above T5 and use of an ignition source in proximity to an anesthetic.*
   - **NO**
     - Proceed but reassess for changes in fire risk frequently.
   - **YES**
     - Nurses and surgeons avoid pooling of alcohol based skin preparations and allow adequate drying time. Communication between surgeon and anesthesia professional prior to initial use of electrocautery.

2. **Does patient require oxygen supplementation?**
   - **NO**
     - Room air sedation.
   - **YES**
     - Is >30% oxygen concentration required to maintain oxygen saturation?
       - **NO**
         - Use delivery device such as blender or common gas outlet to maintain oxygen below 30%.
       - **YES**
         - Secure airway with endotracheal tube or supraglottic device.

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*Although securing the airway is preferred, for cases where using a device is undesirable or not feasible, oxygen accumulation may be minimized by air insufflation over the face and open draping to provide wide exposure of the surgical site to the atmosphere.*

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*The following organizations have indicated their support for APSF's efforts to increase awareness of the potential for surgical fires in at-risk patients: American Society of Anesthesiologists, American Association of Nurse Anesthetists, American Academy of Anesthesiology Assistants, American College of Surgeons, American Society of Operating Room Nurses, American Association of Respiratory Care, National Association of Anesthesia Technologists and Technicians, American Society for the Prevention of Blindness, American Society of Healthcare Risk Management, American Society of PeriAnesthesia Nurses, American Society of Anaesthesiologists, American Academy of Orthopaedic Surgeons, American Society for Wound Healing, American College of Emergency Physicians.*

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FDA Surgical Fire Prevention

**U.S. Food and Drug Administration**

**Safe Use Initiative: FDA-Sponsored Stakeholder Meeting on Surgical Fire Prevention**

www.fda.gov/Drugs/DrugSafety/ucm239511.htm

On October 22, 2010, the Food and Drug Administration held a Safe Use Initiative Stakeholder Meeting on Surgical Fire Prevention. The workshop was organized by the Center for Drug Evaluation and Research at the FDA and the Radiological Health Division of the FDA's Office of the Commissioner.

**Background**

Surgical fires are rare events but can result in serious morbidity and death. Based on the best available data from ECRI Institute, a not-for-profit organization with a 30-year history of investigating operating room fires, approximately 500 to 600 occur in the United States each year. Surgical fires occur during handling of one or more of the elements of the fire triangle—oxygen, fuel source, and heat source. The fuel source (drapes, alcohol-based surgical skin preparation products, and the oxidizer (e.g., oxygen, air, or oxygen and air) are all components present in the surgical field. Surgical fires are “never events” so-called because they are serious events that should never occur; they are 100% preventable. In 2003, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a sentinel event alert bulletin to ambulatory surgical sites and some hospitals. The bulletin was related to fires that occur during operative and invasive procedures and serves to raise the level of awareness of the dangers of surgical fires. The Joint Commission recommended that healthcare organizations prevent surgical fires by revising policies and procedures for nonsterile instruments and equipment. The
Pa Patient Safety Authority

Pennsylvania Patient Safety Advisory

OR Fire Prevention Video Available

ASA Updated February 2013

Practice Advisory for the Prevention and Management of Operating Room Fires

practiceadvisory.org/Home/For-Members/Practice-Management/Practice-Parameters/#fires
AORN Fire Risk Assessment Tool

Fire Risk Assessment Tool

Instructions for use

Purpose
To assist the perioperative team in determining and communicating the potential fire risk for each individual patient.

Instructions for use
1. This risk assessment is intended to be used with the Policy and Procedure which contains additional information on fire prevention.
2. The circulating nurse will complete the risk assessment to determine the risk level designation. The risk level designation of A, B, C, D, E is determined by the code assigned to each of the critical questions below that have an affirmative response. The results may be any one letter or any combination of the letters.
3. The circulating nurse will report those having a positive response to the surgical team during the “Time Out” as A, B, C, D, or E or any combinations of the letters.

H&P 952

- H&P must be on the chart before the patient goes to surgery
- Must make sure H&P is no older than 30 days
- Must update the day of surgery before surgery except in emergencies
- Must be on chart 24 hours after admission
- P&P must specify what is an emergency
  - See tag 358 on H &P in medical records section
Consent 955

- Informed consent is in three sections of the CoPs and each is different and not a repeat
- Third section in the surgery chapter
- Surgical services
- Consent must be in chart before surgery
  - Exception for emergencies
- Tag 464 in medical records section sets out the mandatory elements that must be in a consent form

Informed Consent MR Mandatory Elements

- Name of hospital
- Name of procedure or treatment
- Name of responsible practitioner who is performing
- Statement that benefits, material risks and alternatives were explained
- Signature of patient with date and time
Informed Consent  955

- Recommend anesthesia consent
- Lists elements for well designed process, which are the optional elements
- Specifies what must be in the consent policy
- Who can obtain
- Which procedures need consent

Informed Consent Policy

- When is surgery an emergency
- Content of consent form
- Process to obtain consent
- If consent obtained outside hospital how to get it into medical records
Informed Consent 955

- Must disclose if residents, RNFA, Surgical PAs Cardiovascular Techs are doing important tasks
- Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines
- But requirement to have this in writing in under optional list or well designed list

Surgery Equipment A-0956

- Call-in system
- Cardiac monitor
- Defibrillator
- Aspirator (suction equipment)
- Trach set (cricothyroidotomy is not a substitute)
- TJC PC.03.01.01 includes this plus ventilator, and manual breathing bags
OR Register 958

- Patient’s name, id number
- Date of surgery
- Total time of surgery
- Name of surgeons, nursing personnel, anesthesiologist, and assistants
- Type of anesthesia
- Operative findings, pre-op and post-op diagnosis
- Age of patient
- See TJC RC.02.01.03 which are now the same
Operative Report 959

- Name and id of patient
- Date and time of surgery
- Name of surgeons, assistants
- Pre-op and post-op diagnosis
- Name of procedure
- Type of anesthesia

Operative Report A-959

- Complications and description of techniques and tissue removed
- Grafts, tissue, devices implanted
- Name and description of significant surgical tasks done by others (see list-opening, closing, harvesting grafts)
CMS Hospital CoPs Section on PACU

PACU 957 2014

- Standard: Must be adequate provisions for immediate post-op care
- Must be in accordance with acceptable standards of care, for all patients including same day surgery patients
  - Such as following the ASPAN standards of care and practice
- Separate room with limited access
- P&P specify transfer requirements to and from PACU
2014 Changes to PACU Section

CMS Manual System
Pub. 100-07 State Operations
Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal
(Advance Copy)
Date:

SUBJECT: Revised Appendix A: Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for various provisions of 42 CFR 482.23(c), concerning medication administration, and 42 CFR 482.51(b)(4), concerning post-operative patient care.

NEW/REVISED MATERIAL - EFFECTIVE DATE: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicsized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new-revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) - (Only One Per Row)

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<td>Appendix A/ A-0400, §482.23(c) Standard: Preparation and Administration of Drugs: §482.23(c)(1)(a), (c)(1)(b), &amp; (c)(2)</td>
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<td>Appendix A/ A-0957, §482.51(b) Standard: Delivery of Services: Immediate Post-operative Care: §482.51(b)(4)</td>
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A.0957

§482.51(b)(4) - There must be adequate provisions for immediate post-operative care.

Interpretive Guidelines §482.51(b)(4)

Adequate provisions for immediate post-operative care means:

- Post-operative care must be provided to all surgical patients, including same-day surgery patients, in accordance with acceptable standards of practice.
- A post-operative care area, usually referred to as the post-anesthesia care unit (PACU), is a separate area of the hospital. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the PACU. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the PACU includes, but is not limited to:
  - Level of activity;
  - Respiration;
  - Blood pressure;
  - Level of consciousness;
  - Level of pain;
  - Patient color; and
PACU 957  2014

- PACU assessment includes level of activity, level of pain, respiration, BP, LOC, patient color, Aldrete.
- If not sent to PACU then close observation of patient until has gained consciousness by a qualified RN.
- Surveyor is instructed to observe care provided in the PACU to make sure they are monitored and assessed prior to transfer or discharge.
- Will look to determine if hospital has system to monitor needs of post-op patient transferred from PACU to other areas of the hospital.

Post-Operative Monitoring  2014

- Hospitals are expected to have P&P on the minimum scope and frequency of monitoring in post-PACU setting.
- Must be consistent with the standard of care.
- Concerned about post-op patients receiving opioids.
- Concern about risk for over-sedation and respiratory depression.
- Once out of PACU not monitored as frequently.
- Need appropriate assessment to prevent these complications (See Tag 405).
Perianesthesia Nursing Standards

Serving nurses practicing in all phases of preanesthesia and perianesthesia care, ambulatory surgery, and pain management.

FAQs
Submit Questions
Fatigue Checklist
Clinical Narratives
Position Statements
Practice Resources
Clinical Guidelines
ASPAN Standards
Competency Based Orientation
Competency Based Orientation (CAPP)
Patient Classification
Safety in Practice
CSP Abstracts

2012-2014 Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements

www.aspan.org/Clinical-Practice/ASPAN-Standards

Since its inception in 1964, the American Society of PeriAnesthesia Nurses (ASPAN) Standards of PeriAnesthesia Nursing Practice has provided a framework for the expanding scope of care for a diverse patient population across all periAnesthesia settings. The Standards are reviewed and updated on an ongoing basis and are republished biannually. Each revised edition incorporates current evidence-based practice, emerging regulatory requirements, and reflects changing technology and nursing practice.

The 2012-2014 edition of the ASPAN Standards spells a new title: Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements. This updated text contains principles of periAnesthesia practice, periAnesthesia practice standards, evidence-based clinical practice guidelines, position statements, practice recommendations, resources from partnering organizations and interpretive statements which provide clarity and definition to key elements of the standards.

New content in this publication includes principles of safe periAnesthesia practice, a practice recommendation for care of the adult patient with obstructive sleep apnea, a revised practice recommendation for family visitation in periAnesthesia care unit and a position statement on substance abuse in the periAnesthesia setting.
The CMS Anesthesia Standards
ASA Guidelines and Standards

Anesthesia 1000

- Must be provided in well organized manner under qualified doctor (an example is the Director of Anesthesiology)
  - Even in states where CRNAs do not need to be supervised, need qualified doctor to be medical director of anesthesia (not in CAH)
  - Final revision changed the section on the criteria for the qualification of the anesthesia director
  - Service responsible for all anesthesia administered in the hospital
  - Optional service and must be integrated into hospital QAPI
http://asahq.org

Anesthesia Definitions 1000

- **Anesthesia** involves administration of medication to produce a blunting or loss of:
  - Pain perception (analgesia)
  - Voluntary and involuntary movements
  - Autonomic function
  - Memory and or consciousness

- **Analgesia** (pain) is use of medication to provide pain relief thru blocking pain receptor in peripheral and or CNS where patient does not lose consciousness but does not perceive pain.
Anesthesia exists on a continuum

There is not a bright line that distinguishes when the drug's properties from analgesia to anesthesia

CMS has definitions of what constitutes anesthesia: general anesthesia, regional (spinal or epidural), monitored anesthesia care (MAC), including deep sedation

For the most part, definitions follow the ASA practice guidelines

- Anesthesiology 2002; 96:1004-17

- **General anesthesia**: a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory support is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. For example, a patient undergoing major abdominal surgery involving the removal of a portion or all of an organ would require general anesthesia in order to tolerate such an extensive surgical procedure. General anesthesia is used for those procedures when loss of consciousness is required for the safe and effective delivery of surgical services;

- **Regional anesthesia**: the delivery of anesthetic medication at a specific level of the spinal cord and/or peripheral nerves, including epidurals and spinals and other central neuraxial nerve blocks. is used when loss of consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required. Given the potential for the conversion and extension of regional to general anesthesia in certain procedures, it is necessary that the administration of regional and general anesthesia be delivered or supervised by a practitioner as specified in 42 CFR 482.52(a).
Monitored Anesthesia Care (MAC)

- Anesthesia care that includes monitoring of patient by a person qualified to give anesthesia (like anesthesiologist or CRNA)
- Include potential to convert to a general or regional anesthetic (MAC)
- Deep sedation/analgesia is included in a MAC
- Deep sedation where drug induced depression of consciousness during which patient can not easily be aroused but responds purposefully following repeated or painful stimulus
  - Removed: An example of deep sedation is when Propofol is used for a screening colonoscopy

Definition of MAC by CMS

- Monitored anesthesia care (MAC): anesthesia care that includes the monitoring of the patient by a practitioner who is qualified to administer anesthesia as defined by the regulations at §482.52(a). Indications for MAC depend on the nature of the procedure, the patient’s clinical condition, and the potential need to convert to a general or regional anesthetic. Deep sedation/analgesia is included in MAC.

  - Deep sedation/analgesia: a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Because of the potential for the inadvertent progression to general anesthesia in certain procedures, it is necessary that the administration of deep sedation/analgesia be delivered or supervised by a practitioner as specified in 42 CFR 482.52(a).
Anesthesia Services Pain Bucket 1000

- Services **not** subject to anesthesia administration and supervision requirements
  - **Topical** or **local anesthesia**; application or injection of drug to stop a painful sensation
  - **Minimal sedation**; drug induced state in which patient can respond to verbal commands such as oral medication to decrease anxiety for MRI
  - **Moderate or conscious sedation**; in which patients respond purposely to verbal commands, either alone or by light tactile stimulation

Definitions of Analgesia (Pain)

- **Moderate sedation/analgesia** (“Conscious Sedation”): a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. CMS, consistent with ASA guidelines, does not define moderate or conscious sedation as anesthesia (71FR 68690-1).

- **Minimal sedation**: a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilator and cardiovascular functions are unaffected. This is also not anesthesia.

- **Topical or local anesthesia**: the application or injection of a drug or combination of drugs to stop or prevent a painful sensation to a circumscribed area of the body where a painful procedure is to be performed. There are generally no systemic effects of these medications, which also are not anesthesia, despite the name.
Anesthesia Services 1000

- Rescue capacity
  - Sedation is a continuum
  - It is not always possible to predict how any individual patient will respond
  - So may need to rescue by one with expertise in airway management and advanced life support
  - Must have procedures in place to rescue patients whose sedation becomes deeper than initially intended

Anesthesia Services 1000

- TJC has standards also on how to safely perform moderate or procedural sedation and anesthesia in the PC chapter
- Still need to do a **pre-sedation assessment** and post-sedation assessment but since not anesthesia not a pre or post-anesthesia assessment
- Also references the need to follow **nationally standards of practice** such as ASA (American Society of Anesthesiologists), ACEP (American College of Emergency Physicians) and ASGE (American Society for GI Endoscopy), AGA, ENA, ADA, etc.
  - Listed at the end as additional resources
One Anesthesia Service 1000

- Anesthesia services must be under one anesthesia services under direction of qualified physician no matter where performed through out the hospital

- Including if done in any of the following:
  - Operating room for both inpatients and outpatients
  - OB
  - Radiology (interventional radiology),
  - ED
  - Psychiatry (ECT)
  - Endoscopy, pain management clinics etc.

Anesthesia Services under Qualified Director

- Anesthesia services must be under the direction of one individual who is a qualified doctor (1000)

- Need to have medical staff rules and regulations establishing the criteria for the qualifications for the director of anesthesia services

- MS establishes this criteria for director's qualifications

- The board approves after consideration of the medical staff's recommendation

- Must be consistent with state law and acceptable standards of practice
Interpretation from CMS

- The regulation states, “…under the direction of a qualified doctor of medicine or osteopathy.” This means the anesthesia service can be directed by any type of MD or DO who is qualified.

- You are correct that in most hospitals with an anesthesia service, an anesthesiologist would “generally” be the director. However, some hospitals do not have an anesthesiologist on staff. If a hospital provides any type of anesthesia service, the hospital would have to find an MD or DO that has the qualifications to be the Director of Anesthesia Services in the hospital.

- The hospital would establish criteria for determining that a particular MD or DO was qualified to be the director (such as knowledge of anesthesia procedures, anesthesia/sedation/analgesia medications, State scope of practice rules, National Standards of practice, administrative skills, management, and other criteria). Hospitals already must establish criteria for determining whether a physician is qualified to provide care and which types of care. Therefore, a hospital should be able to ensure that whichever MD or DO they select as the Director of Anesthesia Services is qualified for that position.

CMS Manual

The anesthesia services must be under the direction of one individual who is a qualified doctor of medicine (MD) or doctor of osteopathy (DO). Consistent with the requirement at §482.12(a)(4) for it to approve medical staff bylaws, rules and regulations, the hospital’s governing body approves, after considering the medical staff’s recommendations, medical staff rules and regulations establishing criteria for the qualifications for the director of the anesthesia services. Such criteria must be consistent with State laws and acceptable standards of practice.
Anesthesia Services Who Can Give? 1000

- Hospital needs to have policies and procedures that are based on nationally recognized guidelines as to whether it is anesthesia or analgesia
  - Be sure to cite standard such as ASA, ASGE, ACEP etc.
- Hospitals need to determine if sedation done in the ED or procedures rooms is anesthesia or analgesia
- Must take into consideration for P&P characteristics of patients served, skill set of staff and what medications are being used
- This standard also sets forth the supervision requirements for staff who administer anesthesia

Supervision and Privileges 1000

- P&Ps need to establish minimum qualifications and supervision requirements including moderate sedation
  - MS credentialing standards and the nursing standards exist to make sure staff are qualified and competent
  - Want to make sure that staff administering drugs are qualified
  - Drugs must be given with accepted standards of practice
  - MS bylaws address criteria for determining privileges and to apply the criteria to those who request privileges
### Supervision and Privileges 1000

- If nursing staff give IV medication then must have be competent in specified areas (amended 2013 and again in 2014 so follow P&P)
  - This is one of the education requirements of CMS
  - Also training on restraint and seclusion, infection control and hand hygiene, abuse and neglect, advance directives, organ donation, IV and blood and blood products and ED staff with ED common emergencies, timing of medication, medication error, ADE and drug incompatibilities
- Must have P&P to look at adverse events, medication errors and other safety and quality indicators
  - Must periodically re-evaluate these and include in PI

### Anesthesia Services 1000

- Hospital Medical Staff determine the qualifications for the Director of Anesthesia
- Must be in accordance with the state law and acceptable standards of practice
- Anesthesia service is responsible for developing policies and procedures governing all categories of anesthesia service
- This includes the minimum qualification for each category of practitioner who is permitted to provide anesthesia services
Anesthesia Survey Procedure A-1000

- Surveyor is supposed to ask for a copy of the organizational chart for anesthesia
- Make sure MD or DO has authority and responsibility for directing anesthesia services throughout the hospital
- Anesthesia must be integrated into the QAPI program
  - Every department has a role in PI including anesthesia
  - See Anesthesia Quality Institute (AQI) which is home to national anesthesia clinical outcomes registry (NACOR) and has a list of things to measure

What PI Do You Measure??

**Process indicators:** on time starting, prophylactic antibiotic administration, adherence to central line bundle, normothermia in the PACU, number of patient complaints

Are anesthesia staff educated on the CMS grievance and TJC Complaint standard?  
Yes...No

**Clinical outcome indicators:** patient satisfaction, number of cases completed without any event, number of each critical event occurring by location (high spinal, epidural hematoma, infection after regional, perioperative MI, death, unplanned difficult airway, local anesthesia toxicity, medication error, incorrect patient, OR fire, transfusion reaction, new stroke, visual loss, Intraoperative awareness, peripheral neurologic deficit, etc)

CMS 2011 outpatient surgical measure is antibiotic timing and is described by CMS as “Percentage of outpatients having surgery who were given the right kind of antibiotic at the right time (within one hour before surgery) to help prevent infection of surgical wounds.” This measure is already in place for inpatient data and will be used in conjunction to obtain a more comprehensive view of the quality of care being provided in hospitals.

**Case information:** no untoward event, significant delay, case cancelled, equipment problem, extended PACU stay, unanticipated ICU admission, unanticipated hospital admission, death, cardiac arrest, asphyxia, malignant hyperthermia, transfusion reaction, visual loss, stroke, PONV, PACU pain control in adequate, hypotension or hypothermia in the PACU, vascular access complication, infection after regional anesthesia, high spinal, postdural puncture headache
What Do You Measure?

<table>
<thead>
<tr>
<th>Reason for Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>An-1 CNS complication</td>
</tr>
<tr>
<td>An-2 Peripheral neurologic deficit</td>
</tr>
<tr>
<td>An-3 AMI post anesthesia</td>
</tr>
<tr>
<td>An-4 Cardiac Arrest post anesthesia</td>
</tr>
<tr>
<td>An-5 Respiratory Arrest post anesthesia</td>
</tr>
<tr>
<td>An-6 Death w/in 48 hours of anesthesia</td>
</tr>
<tr>
<td>An-7 Unplanned adm w/in 24 hours d/t anesthesia</td>
</tr>
<tr>
<td>An-8 Unplanned adm to ICU w/in 24 hours of anes</td>
</tr>
<tr>
<td>An-9 Pulmonary Edema w/in 24 hrs of anesthesia</td>
</tr>
<tr>
<td>An-10 Aspiration pneumonitis w/in 48 hours</td>
</tr>
<tr>
<td>An-13 Anesthesia Awareness</td>
</tr>
<tr>
<td>M-1 Death w/i 48 hours of surgical/invasive proc</td>
</tr>
<tr>
<td>M-2 Intra-operative death</td>
</tr>
<tr>
<td>M-3 Death w/i immediate recover time of surg/inv</td>
</tr>
<tr>
<td>M-4 Death w/i 48 hours of IV sedation</td>
</tr>
<tr>
<td>S-1 Unscheduled admission following outpt proc</td>
</tr>
</tbody>
</table>

What Do You Measure?

| S-1 Unscheduled admission following outpt proc |
| S-2 Unplanned return to surgery |
| S-3 Foreign object/material found/left in wound |
| S-4 Burn or non-surgical trauma |
| S-5 Wrong procedure or wrong pt |
| S-9 Nerve damage noted post-operatively |
| S-12 Any untoward patient reaction in OR/PACU/ENDO |
| S-16 Post Operative Complication |
| S-17 Path/operative dx mismatch |
| S-20 Accidental puncture or laceration during proc |
| S-23 Mismatch pre and post op diagnosis |
| Modsed-1 Reversal Agent Administered |
| Modsed -2 Hemodynamic Instability |
| Modsed -3 Extended recovery time |
| Modsed -4 Unplanned Admission |
| Modsed -5 Unplanned Surgery |
| Modsed-7 Decreased O2 Sat |
### AQI Has Data Capture Sheets

**Anesthesia Quality Improvement PACU Discharge**

<table>
<thead>
<tr>
<th>Case Info</th>
<th>Anesthesia type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date</strong></td>
<td>Provider ID</td>
</tr>
<tr>
<td><strong>MR #</strong></td>
<td>CRNA ID</td>
</tr>
<tr>
<td><strong>ASA Class</strong></td>
<td>Additional provider</td>
</tr>
</tbody>
</table>

- **Patient is awake and able to contribute to assessment:** [ ] Yes [ ] No
- **Patient Physical Exam:***
  - Mental Status at baseline (Y/N)
  - Vital Signs at baseline (Y/N)
  - Airway patency at baseline (Y/N)
- **Nausea or vomiting requiring treatment:** [ ] Reason
- **Did the patient experience an unexpected event during perioperative care?** [ ] Yes [ ] No
  - Unplanned ICU admission
  - Unplanned hospital admission
  - Intraoperative awareness
  - Epidural hematoma
  - Perioperative neurological deficit
  - Corneal abrasion
  - Agitation requiring treatment
  - Seizure
  - Pain score (10-point VAS scale): [ ] on PACU admission [ ] Highest pain score [ ] Pain score at time of assessment

[www.aqihq.org/qualitymeasurementtools.aspx](http://www.aqihq.org/qualitymeasurementtools.aspx)

### Anesthesia Quality Improvement Intra-Operative

<table>
<thead>
<tr>
<th>Case Info</th>
<th>Anesthesia type</th>
</tr>
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<tbody>
<tr>
<td><strong>Date</strong></td>
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<td>CRNA ID</td>
</tr>
<tr>
<td><strong>ASA Class</strong></td>
<td>Additional provider</td>
</tr>
</tbody>
</table>

- **NO UNTOWARD EVENT **: [ ] Death (Excludes ASA 5 patients presenting for harvesting)
- **Case Cancelled**
- **Case Delayed**
- **Incorrect procedure**
- **Pulmonary edema**
- **Hypotension requiring unanticipated therapy with a continuous infusion of pressor agents**
- **Unanticipated difficult airway**
- **Anaphylaxis**
- **High spinal**
- **Vascular access complication - vessel injury**
- **Pulmonary edema**
- **Hypotension requiring unanticipated therapy with a continuous infusion of pressor agents**
- **Unanticipated difficult airway**
- **Anaphylaxis**
- **High spinal**
- **Vascular access complication - vessel injury**

[www.aqihq.org/qualitymeasurementtools.aspx](http://www.aqihq.org/qualitymeasurementtools.aspx)
Anesthesia Survey Procedure 1000

- Surveyor to look in directors file
- Will review job or position description of MD/DO director and look for appointment
- Will make sure privileges and qualifications are consistent with the criteria adopted by the board
- Will confirm directors responsibilities include;
  - Planning, directing, and supervision of all activities
  - Removed section on establishing staffing schedules
  - Evaluate the quality and appropriateness of anesthesia services provided to patients as part of PI process
Anesthesia Survey Procedure 1000

- Surveyor is supposed to request and review all of the anesthesia policies and procedures.
- Will make sure the anesthesia are applied to everywhere in the hospital where anesthesia services are provided.
- Will make sure the P&P indicate the necessary qualifications that each clinical practitioner must possess in order to administer anesthesia as well as moderate sedation or other forms of analgesia.

Anesthesia Survey Procedure 1000

- Surveyor is to make sure that the clinical applications are considered involving analgesia such as moderate sedation as opposed to anesthesia.
- Document what national guidelines are being followed.
- The surveyor will make sure the hospital has an adverse event system related to both anesthesia and analgesia.
  - Are they tracked and acted upon (incident report, RCA, etc.)
Organization and Staffing 1001

- Anesthesia (general, regional, MAC including deep sedation) can only be administered by:
  - Qualified anesthesiologist or CRNA
  - Anesthesiology assistant (AA) under the supervision of anesthesiologist who is immediately available if needed
  - Dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under state law
  - A MD or DO other than anesthesiologist (must be qualified)
    - Lots of discussion on this
    - Hospital needs to follow standards of anesthesia care when establishing P&P governing anesthesia administration by these types of practitioners as well as MDs or DOs who are not anesthesiologists

Who Is Qualified to Give Anesthesia

- Note: Chart Removed from 4th Revision

- Hospital Anesthesia Services
  - Anesthesia
    - General
    - Regional
    - MAC
    - Deep Sedation
  - Analgesia/Sedation
    - Topical
    - Local
    - Minimal
    - Moderate

- Opt-Out State?
  - Yes
  - No

- No MD supervision required for CRNA
- MD supervision required for CENA

- To be administered by appropriately trained medical practitioner within scope of practice
Who Can Administer Anesthesia

Administration by an MD/DO/dentist/oral surgeon/podiatrist

The hospital’s anesthesia services policies must address the circumstances under which an MD or DO who is not an anesthesiologist, a dentist, oral surgeon or podiatrist is permitted to administer anesthesia. In the case of a dentist, oral surgeon or podiatrist, administration of anesthesia must be permissible under State law and comply with all State requirements concerning qualifications. Hospitals should conform to generally accepted standards of anesthesia care when establishing policies governing anesthesia administration by these types of practitioners as well as MDs or DOs who are not anesthesiologists.

Organization and Staffing  1001

- CRNA can be supervised by the operating surgeon or the anesthesiologist
- CRNA may not require supervision if state got an exemption from supervision
- Governor sends a letter to CMS requesting this after attesting that the State Medical Board and Nursing Board were consulted and in best interests of the state
- List of 17 state exemptions at www.cms.hhs.gov/CFCsAndCoPs/02_Spotlight.asp
  - Iowa, Nebraska, Idaho, Minnesota, New Hampshire, New Mexico, Kansas, North Dakota, Washington, Alaska, Oregon, South Dakota, Wisconsin, Montana, Colorado, and California
Administering 1001

- Need P&P concerning who may administer analgesia
  - Topical, local, minimal sedation and moderate sedation
  - Consistent with scope of practice set by state law
- General, regional, MAC and deep sedation can only be administered by the 5 categories mentioned
- Hospital must follow generally accepted standards of anesthesia care if anyone other than anesthesiologist, CRNA, or AA does
- Need policy on supervision also

Who Can Administer Anesthesia 1001

- CRNA can administer anesthesia if under the operating surgeon or by an anesthesiologist
- If supervised by an anesthesiologist must be immediately available
- What does immediately available mean?
- Anesthesiologist must be physically located in the same area as the CRNA
- Example: in the same operative suite, same procedure room, same L&D unit and nothing prevents from immediate hands on intervention
CRNA Supervision

- No supervision if in one of the 17 states that has opted out and so no longer requires it.
- Otherwise must be supervised by:
  - Operating practitioner who is performing the procedure or
  - Anesthesiologist who is immediately available.
- Immediately available means anesthesiologist must be located within the same area of the CRNA and not occupied to prevent him/her from immediately conducting hands on intervention if needed.
  - If CRNA in OR then anesthesiologist must be somewhere in the OR suite.

Administration by a CRNA

Unless the hospital is located in a State that has chosen to opt out of the CRNA supervision requirements, a CRNA administering general, regional and monitored anesthesia must be supervised either by the operating practitioner who is performing the procedure, or by an anesthesiologist who is immediately available.

Hospitals should conform to generally accepted standards of anesthesia care when establishing policies for supervision by the operating practitioner. An anesthesiologist is considered “immediately available” when needed by a CRNA under the anesthesiologist’s supervision only if he/she is physically located within the same area as the CRNA, e.g., in the same operative suite, or in the same labor and delivery unit, or in the same procedure room, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.
Don’t Want a False Claims Act Lawsuit

UC-Irvine to Pay $1.2M to Settle Claims of Improper Supervision for Anesthesia
Written by Molly Gamble | March 27, 2013

The Regents of the University of California, the university’s governing body, has agreed to pay $1.2 million to resolve allegations that anesthesia was routinely administered at University of California-Irvine by healthcare providers when a supervisory anesthesiologist was not present, according to a news release from the law offices of Louis J. Cohen, PC, which represented the whistleblower in this case.

The settlement stems from a 2008 lawsuit filed by a former UC-Irvine anesthesiologist. His complaint triggered a “multi-year” investigation by the Department of Justice, according to the release.

The complaint alleged that certified registered nurse anesthetists or residents at UC-Irvine administered anesthesia in many instances when the supervisory anesthesiologist was in another facility, which violates federal regulations.

The complaint also alleged that postoperative evaluations would routinely be provided by unsupervised or unlicensed residents, which is also a violation of federal regulations.

A comment from UC-Irvine was not provided in the release.

Improper Supervision of Anesthesia Services

- A federal qui tam whistle blower lawsuit was filed by former anesthesiologist and professor Dr. Dennis O’Connor
- Investigated by the US Dept of Justice
- Hospital in California pays $1.2 million to resolve claims of improper supervision of anesthesia services
- Said no supervisory anesthesiologist was present or immediately available in violation of federal law
- Anesthesia records pre-filled out to make it look like anesthesiologist were there
Some states have a practice act for AAs or anesthesiology assistants.

An AA may administer anesthesia only when under the direct supervision of an anesthesiologist only.

Anesthesiologist must also be immediately available if needed.

This means physically in the same department and not occupied in a way to prevent immediate hands on intervention if needed.

Administration by an anesthesiologist’s assistant

An anesthesiologist’s assistant may administer anesthesia when under the direct supervision of an anesthesiologist. The anesthesiologist must be immediately available if needed. An anesthesiologist is considered “immediately available” to assist the anesthesiologist’s assistant under the anesthesiologist’s supervision only if he/she is physically located within the same area as the anesthesiologist’s assistant, e.g., in the same operative suite, or in the same labor and delivery unit, or in the same procedure room, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.

An anesthesiologist’s assistant is defined in §410.69(b) as a “...person who – (1) works under the direction of an anesthesiologist; (2) is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and (3) is a graduate of a medical school-based anesthesiologist’s assistant education program that – (A) is accredited by the Committee on Allied Health Education and Accreditation; and (B) includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.”
Anesthesia Services Policies 1001

- MS bylaws or R/R must include criteria for determining anesthesia privileges
- Board must approve the specific anesthesia service privilege for each practitioner who does anesthesia services
- Must address the type of supervision required, if any, and must specify who can supervise CRNA (unless exempted)
- Privileges must be granted in accordance with state law and hospital policy
Supervision by Operating Surgeon 1002

- If hospital allows supervision by operating surgeon of CRNAs
- Medical staff bylaws or R/R must specify for each category of operating practitioners
- The type and complexity of the procedures that the category of practitioner may supervise
- See resources at the end that discuss standards of practice on credentialing and privileging

Survey Procedure   1001

- Surveyor is to review the qualifications of individuals allowed to give anesthesia to make sure they are qualified
- Make sure licenses and certifications are current
- Determine if state has opted out for CRNA supervision
- Review the hospital P&P to make sure supervision of CRNA and AA meets requirements
- Review qualifications of other anesthesia services to make sure they are consistent with the hospital anesthesia policies
Anesthesia Services and Policies 1002

- Anesthesia must be consistent with needs of patients and resources
- P&P must include delineation of pre-anesthesia and post-anesthesia responsibilities
- Must be consistent with the standards of care
- Policies include;
  - Consent
  - Infection Control measures
  - Safety practices in all areas
  - How hospital anesthesia service needs are met

Anesthesia Policies Required 1002

- Policies required (continued);
  - Protocols for life support function such as cardiac or respiratory emergencies
  - Reporting requirements
  - Documentation requirements
  - Equipment requirements
  - Monitoring, inspecting, testing and maintenance of anesthesia equipment
  - Pre and post anesthesia responsibilities
Pre-Anesthesia Assessment 1003

- Pre-anesthesia evaluation must be performed with 48 hours prior to the surgery
  - Including inpatient and outpatient procedures
- For regional, general, and MAC including deep sedation
- Not required for moderate sedation but still need to do pre-sedation assessment
- Pre-anesthesia assessment must be done by some one qualified person to administer anesthetic (non-delegable)

Pre-anesthesia Evaluation 1003

- Must have policies to make sure the pre-anesthesia guidelines are met
- Pre-anesthesia evaluation must be completed, documented and done by one qualified to administer anesthesia within 48 hours
  - Can not delegate the pre-anesthesia assessment to someone who is not qualified which is 5 categories mentioned
- Must be done within 48 hours of surgery or procedure
5 Qualified to do Pre-Anesthesia Assessment

- Anesthesiologist
- CRNA under the supervision of operating surgeon or anesthesiologist unless state is exempt
- AA under supervision of anesthesiologist
- MD or DO other than an anesthesiologist
- A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law

Pre-anesthesia Evaluation 1003

- Delivery of **first dose of medication** for inducing anesthesia marks end of 48 hour time frame
- Pre-anesthesia assessment must be done for generals, regional, or MAC which includes deep sedation
- If moderate sedation current practice dictates a pre-procedure assessment but not a pre-anesthesia assessment
- See TJC standards at the end of presentation on presedation assessment for patients having moderate sedation
Pre-anesthesia Evaluation 1003

- CMS says pre-anesthesia must be done within 48 hours of procedure or surgery
- However, some of the elements in the evaluation can be collected prior to the 48 hours time frame but it can never be more than 30 days (new)
  - If you saw a patient on Friday for Monday surgery would need to show that on Monday there were no changes
  - CMS also specifies the four of the six required elements that can be performed within 30 days

Pre-Anesthetic Assessment 1003

- Must include;
  - Review of medical history, including anesthesia, drug, and allergy history (within 48 hours)
  - Interview and exam the patient
    - Within 48 hours and rest are updated in 48 hours but can be collected within 30 days
  - Notation of anesthesia risk (such as ASA level)
  - Potential anesthesia problems identification (including what could be complication or contraindication like difficult airway, ongoing infection, or limited intravascular access)
Pre-Anesthetic Assessment 1003

- Pre-anesthetic Assessment to include (continued);
  - Additional data or information in accordance with SOC or SOP
    - Including information such as stress test or additional consults
  - Develop plan of care including type of medication for induction, maintenance, and post-operative care
  - Of the risks and benefits of the anesthesia
ASA Physical Status Classification System

- ASA PS I – normal healthy patient
- ASA PS II – patient with mild systemic disease
- ASA PS III – patient with severe systemic disease
- ASA PS IV – patient with severe systemic disease that is a constant threat to life
- ASA PS V – moribund patient who is not expected to survive without the operation
- ASA PS VI – declared brain-dead patient whose organs are being removed for donor purposes

Survey Procedure Pre-anesthesia Evaluation

- Surveyor to review sample of inpatient and outpatient records who had anesthesia
- Make sure pre-anesthesia evaluation done and by one qualified to deliver anesthesia
- Determine the pre-anesthesia evaluation had all the required elements
- Make sure done within 48 hours before first does of medication given for purposes of inducing anesthesia for the surgery or procedure
- ASA and AANA has pre-anesthesia standards that hospitals should be familiar with
ASA Guideline  Pre-anesthesia

- Preanesthesia Evaluation
  - Patient interview to assess Medical history, Anesthetic history, Medication history
- Appropriate physical examination
- Review of objective diagnostic data (e.g., laboratory, ECG, X-ray)
- Assignment of ASA physical status
- Formulation of the anesthetic plan and discussion of the risks and benefits of the plan with the patient or the patient’s legal representative

1 www.asahq.org/publicationsAndServices/standards/03.pdf American Society of Anesthesiologist

STANDARDS FOR BASIC ANESTHETIC MONITORING

Committee of Origin: Standards and Practice Parameters
(Approved by the ASA House of Delegates on October 21, 1986, and last amended on October 20, 2010 with an effective date of July 1, 2011)

These standards apply to all anesthetic care although, in emergency circumstances, appropriate life support measures take precedence. These standards may be altered at any time based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. They apply to all general anesthesia, regional anesthesia and monitored anesthesia care. This set of standards addresses only the issue of basic anesthetic monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, 1) some of these methods of monitoring may be clinically impractical, and 2) appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continuous monitoring may be unavoidable. These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

1. STANDARD I

Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

1.1 Objective —
ETCO$_2$ for Moderate and Deep Sedation ASA

3.2.4 During regional anesthesia (with no sedation) or local anesthesia (with no sedation), the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs. During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.


ASA Practice Advisory Preanesthesia Evaluation

http://asahq.org/For-Members/Practice-Management/Practice-Parameters.aspx

**Practice Advisory for Preanesthesia Evaluation**

A Report by the American Society of Anesthesiologists Task Force on Preanesthesia Evaluation

PRACTICE advisories are systematically developed reports that are intended to assist decision-making in areas of patient care where scientific evidence is insufficient to develop an evidence-based model. Practice advisories provide a synthesis of opinion from experts, open forums, and other public sources. Practice advisories report the current state of scientific literature, but are not supported by literature to the same degree as standards or guidelines due to the lack of sufficient numbers of adequately controlled studies.

Advisories are not intended as guidelines, standards, or absolute requirements. The use of practice advisories cannot guarantee a specific outcome. They may be adopted, modified, or rejected according to clinical needs and constraints. Practice advisories are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice.

Definition of Preanesthesia Evaluation

the patient’s medical records, interview, physical examination, and findings from medical tests and evaluations. As part of the preanesthesia evaluation process, the anesthesiologist may choose to consult with other healthcare professionals to obtain information or services that are relevant to perioperative anesthetic care.

Preoperative tests, as a component of the preanesthesia evaluation, may be indicated for various purposes, including but not limited to: (1) discovery or identification of a disease or disorder that may affect perioperative anesthetic care; (2) verification or assessment of an already known disease, disorder, medical or alternative therapy that may affect perioperative anesthetic care, and (3) formulation of specific plans and alternatives for perioperative anesthetic care. For this Advisory, perioperative refers to the care surrounding operations and procedures.

The assessments made in the process of a preanesthesia evaluation may be used to educate the patient, organize resources for perioperative care, and formulate
ASA Standard on Preanesthesia Care

**BASIC STANDARDS FOR PREANESTHESIA CARE**
Committee of Origin: Standards and Practice Parameters
(Approved by the ASA House of Delegates on October 14, 1987, and last affirmed on October 20, 2010)

These standards apply to all patients who receive anesthesia care. Under exceptional circumstances, these standards may be modified. When this is the case, the circumstances shall be documented in the patient’s record.

An anesthesiologist shall be responsible for determining the medical status of the patient and developing a plan of anesthesia care.

The anesthesiologist, before the delivery of anesthesia care, is responsible for:
1. Reviewing the available medical record.
2. Interviewing and performing a focused examination of the patient to:
   2.1 Discussing the medical history, including previous anesthetic experiences and medical therapy.
   2.2 Assessing those aspects of the patient’s physical condition that might affect decisions regarding perioperative risk and management.
3. Ordering and reviewing pertinent available tests and consultations as necessary for the delivery of anesthesia care.
4. Ordering appropriate preoperative medications.
5. Ensuring that consent has been obtained for the anesthesia care.
6. Documenting in the chart that the above has been performed.

Intra-operative Anesthesia Record 1004

- Need policies related to the intra-operative anesthesia record
- Need intra-operative anesthesia record for patients who have general, regional, deep sedation or MAC
- Still need monitoring of moderate sedation before, during, and after but the monitoring required by this section does not apply to that
- See the TJC standards on this
So What’s In Your Policy?

MODERATE SEDATION POLICY FOR NON-ANESTHESIA STAFF

Purpose
The purpose of this policy is to set forth procedures for the management of all patients receiving moderate sedation while undergoing therapeutic, diagnostic or surgical procedures at Methodist Lebonheur Healthcare System Hospitals. These guidelines apply to all locations where moderate sedation is administered. These include, but are not limited to:

Endoscopy Suites
Critical Care areas
Emergency Department
Diagnostic Imaging
Operating Room
Cardiac Cath Lab
Inpatient Unit

Focus
This policy is not intended to apply to the following settings:

General anesthesia
Administration of medication intended solely to counteract anxiety
Administration of medication intended for deep sedation as defined by department(s) of anesthesia
Management of pain before, after, or unrelated to a therapeutic or diagnostic procedure
The use of parenteral or oral medications in the setting of alcohol withdrawal management

Moderate Sedation Toolkit

To assist VA facilities in ensuring that the practice of moderate sedation is safe and effective, the VA National Center for Patient Safety (NCPS) has developed a Moderate Sedation Toolkit for Non-Anesthesiologists, based upon work done at the Durham VAHCS Patient Safety Center of Innovation.

The toolkit is comprised of nine components:

1. Facilitators Guide: This introductory guide describes the moderate sedation toolkit components and provides guidelines for the sedation training facilitator including answers to commonly asked questions.

2. Learning Objectives: These 18 objectives describe the knowledge, skills, and behaviors that should be demonstrated by individuals who administer moderate sedation.

3. Curriculum Guide: This document provides detailed information about moderate sedation practice. Topics include:
   - Introduction - General principles of moderate sedation
   - Pharmacology of commonly used medications
   - Relevant anatomy and physiology
   - Principles of pre-procedural patient assessment and education
   - Monitoring guidelines and techniques
   - Intra-procedure guidelines - required safety equipment and common complication recognition and treatment
   - Special situations and high-risk patients

4. Pre-Procedural Evaluation Template: This template identifies key features of patient evaluation that should be performed prior to beginning a procedure that requires moderate sedation. Facilities may use this as a guide for creating CPSG templates.

5. Moderate Sedation Study Aid: This colorful pocket summary includes key elements of moderate sedation practice, including many of the topics from the curriculum guide. This pocket study aid may be posted for practitioners in all areas where moderate sedation is administered.

6. Moderate Sedation Cognitive Aid: This colorful cognitive aid for anesthesiologists, the pocket study aid, and back reference guide provides bulleted guidelines for managing common complications of moderate sedation (hypotension, hypoxia, bradycardia, tachycardia, hypoglycemia, and aspiration[s] of fluid into sedate). Each complication is addressed in three parts: initial response, follow-up response, and things to consider. It is intended to be available to practitioners in all areas where moderate sedation is administered.

7. Call to Action Card: This template identifies key resources for assistance. Facilities must customize this card for local use. This local version should be posted and clearly visible in all areas where moderate sedation is administered.

8. Painful Procedure Card: Outcomes are available for use in facilities that have the capability to conduct simulation training using a high-fidelity medical simulator. The cases demonstrate the common and important processes encountered during sedation practice.
   - Case 1: Orientation to Simulator and Training Sessions

http://www.patientsafety.gov/pubs.html#sedate
Intra-operative Anesthesia Record 1004

Intra-operative Record must contain the following:

- Include name and hospital id number
- Name of practitioner who administer anesthesia
- Techniques used and patient position, including insertion of any intravascular or airway devices
- Name, dosage, route and time of drugs
- Name and amount of IV fluids
Intra-operative Anesthesia Record 1004

- Intra-operative Record must contain the following (continued):
  - Blood/blood products
  - Oxygenation and ventilation parameters
  - Time based documentation of continuous vital signs
  - Complications, adverse reactions, problems during anesthesia with symptom, VS, treatment rendered and response to treatment
ASA Document Anesthesia Care

STATEMENT ON DOCUMENTATION OF ANESTHESIA CARE

Committee of Origin: Quality Management and Departmental Administration

(Approved by the ASA House of Delegates on October 15, 2003, and amended on October 22, 2008)

Documentation is a factor in the provision of quality care and is the responsibility of an anesthesiologist. While anesthesia care is a continuum, it is usually viewed as consisting of preanesthetic, intraoperative/ procedural anesthesia and postsurgical components. Anesthesia care should be documented to reflect these components and to facilitate review.

The record should include documentation of:

I. Preanesthesia Evaluation:
   A. Patient interview to assess:
      1. Patient and procedure identification.
      2. Verification of admission status (inpatient, outpatient, "short stay", etc.)
      3. Medical history
      4. Anesthetic history
      5. Medication/Allergy history
      6. NPO status
   B. Appropriate physical examination, including vital signs and documentation of any new assessment
   C. Review of objective diagnostic data (e.g., laboratory, ECO, X-ray) and medical records.
   D. Medical consultations when applicable.
   E. Assignment of ASA physical status, including emergent status when applicable.
   F. Formulation of the anesthetic plan and discussion of the risks and benefits of the plan.

Post-anesthesia Evaluation 1005

- Must have policies in place to ensure compliance with the post-anesthesia evaluation requirements
- Post-anesthesia evaluation must be done by someone who is qualified to give anesthesia
  - 5 who are qualified to give as previously mentioned
  - Can not delegate it to a RN, PA, or NP
- Must be done no later than 48 hours after the surgery or procedure requiring anesthesia services

Post-anesthesia Evaluation 1005

- Must be completed as required by hospital policies and procedures
- Must be completed as required by any state specific laws
  - State law can be more stringent but not less stringent so if state wants to require it to be done in 24 instead of 48 hours you must comply
- P&Ps must be approved by the MS
- P&Ps must reflect current standards of care
Post Anesthesia Evaluation 1005

- Document in chart within 48 hours for patients receiving anesthesia services (general, regional, deep sedation, MAC)

- For inpatients and outpatients now
  - So may have to call some outpatients if not seen before they left the hospital
  - Note different for CAH hospitals under their manual under tag 322 (perform before patient leaves the hospital)

- Does not have to be done by the same person who administered the anesthesia

Post Anesthesia Evaluation 1005

- Has to be done only by anesthesia person (CRNA, AA, anesthesiologist) or qualified doctor, dentist, podiatrist, or oral surgeon

- 48 hours starts at time patient moved into PACU or designated recovery area (SICU etc.)

- 48 hour is an outside parameter

- Individual risk factors may dictate that the evaluation be completed and documented sooner than 48 hours
  - This should be addressed by hospital P&P
Post Anesthesia Evaluation 1005

- Evaluation can not generally be done at point of movement to the recovery area since patient not recovered from anesthesia
  - Patient must be sufficiently recovered so as to participate in the evaluation e.g. answer questions, perform simple tasks etc.

Post Anesthesia Evaluation

- For same day surgeries may be done after discharge if allowed by P&P and state law
- If the patient is still intubated and in the ICU still need to do within the 48 hours
  - Would just document that the patient is unable to participate
  - If patient requires long acting anesthesia that would last beyond the 48 hours would just document this and note that full recovery from regional anesthesia has not occurred
Post-Anesthesia Assessment to Include 1005

- Respiratory function with respiratory rate, airway patency and oxygen saturation
- CV function including pulse rate and BP
- Mental status, temperature
- Pain
- Nausea and vomiting
- Post-operative hydration
  - Consider having a form to capture these requirements

Post-Anesthesia Survey Procedure

- Surveyor is review medical records for patients having anesthesia and make sure post-anesthesia evaluation is in the chart
- Surveyor to make sure done by practitioner who is qualified to give anesthesia
- Surveyor to make sure all postanesthesia evaluations are done within 48 hours
- Surveyor to make sure all the required elements are documented for the postanesthesia evaluation
Post Anesthesia ASA Guidelines

- Patient evaluation on admission and discharge from the postanesthesia care unit
- A time-based record of vital signs and level of consciousness
- A time-based record of drugs administered, their dosage and route of administration
- Type and amounts of intravenous fluids administered, including blood and blood products
- Any unusual events including postanesthesia or post procedural complications
- Post-anesthesia visits

STANDARDS FOR POSTANESTHESIA CARE

Committee of Origin: Standards and Practice Parameters
(Approved by the ASA House of Delegates on October 27, 2004, and last amended on October 21, 2009)

These standards apply to postanesthesia care in all locations. These standards may be exceeded based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but cannot guarantee any specific patient outcome. They are subject to revision from time to time as warranted by the evolution of technology and practice.

STANDARD I

ALL PATIENTS WHO HAVE RECEIVED GENERAL ANESTHESIA, REGIONAL ANESTHESIA OR MONITORED ANESTHESIA CARE SHALL RECEIVE APPROPRIATE POSTANESTHESIA MANAGEMENT.

1. A Postanesthesia Care Unit (PACU) or an area which provides equivalent postanesthesia care (for example, a Surgical Intensive Care Unit) shall be available to receive patients after anesthetic care. All patients who receive anesthetic care shall be admitted to the PACU or its equivalent except by specific order of the anesthesiologist responsible for the patient’s care.

2. The medical aspects of care in the PACU (or equivalent area) shall be governed by policies and procedures which have been reviewed and approved by the Department of Anesthesiology.

3. The design, equipment and staffing of the PACU shall meet requirements of the facility’s accrediting and licensing bodies.

STANDARD II

A PATIENT TRANSPORTED TO THE PACU SHALL BE ACCOMPANIED BY A MEMBER OF THE ANESTHESIA CARE TEAM WHO IS KNOWLEDGEABLE ABOUT THE PATIENT’S CONDITION. THE PATIENT SHALL BE CONTINUALLY EVALUATED AND TREATED DURING TRANSPORT WITH MONITORING AND SUPPORT APPROPRIATE TO THE PATIENT’S CONDITION.

STANDARD III

UPON ARRIVAL IN THE PACU, THE PATIENT SHALL BE RE-EVALUATED AND A VERBAL REPORT PROVIDED TO THE RESPONSIBLE PACU NURSE BY THE MEMBER.
ASA Standard Post-anesthesia Care

STANDARDS FOR POSTANESTHESIA CARE
Committee of Origin: Standards and Practice Parameters
(Approved by the ASA House of Delegates on October 27, 2004, and last amended on October 21, 2009)

These standards apply to postanesthesia care in all locations. These standards may be exceeded based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but cannot guarantee any specific patient outcome. They are subject to revision from time to time as warranted by the evolution of technology and practice.

STANDARD I
ALL PATIENTS WHO HAVE RECEIVED GENERAL ANESTHESIA, REGIONAL ANESTHESIA OR MONITORED ANESTHESIA CARE SHALL RECEIVE APPROPRIATE POSTANESTHESIA MANAGEMENT.¹

1. A Postanesthesia Care Unit (PACU) or an area which provides equivalent postanesthesia care (for example, a Surgical Intensive Care Unit) shall be available to receive patients after anesthetic care. All patients who receive anesthesia care shall be admitted to the PACU or its equivalent except by specific order of the anesthesiologist responsible for the patient’s care.

2. The medical aspects of care in the PACU (or equivalent area) shall be governed by policies and procedures which have been reviewed and approved by the Department of Anesthesiology.

3. The design, equipment, and staffing of the PACU shall meet requirements of the facility’s accrediting and licensing bodies.

STANDARD II
A PATIENT TRANSPORTED TO THE PACU SHALL BE ACCOMPANIED BY A MEMBER OF THE ANESTHESIA CARE TEAM WHO IS KNOWLEDGEABLE ABOUT THE PATIENT’S POSTANESTHESIA CARE NEEDS.


ASA Practice Guideline Postanesthesia Care

SPECIAL ARTICLE

Practice Guidelines for Postanesthetic Care
A Report by the American Society of Anesthesiologists Task Force on Postanesthetic Care

PRACTICE guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints. Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice. The Guidelines provide basic recommendations that are supported by analysis of the current literature and by a synthesis of expert opinion, open forum commentary, and clinical feasibility data (Appendix).

A. Definition of Postanesthetic Care
The literature does not provide a standard definition for postanesthetic care. For these Practice Guidelines, postanesthetic care refers to the activities undertaken to manage the patient following completion of a surgical procedure and the concomitant primary anesthetic. anesthesia or sedation and analgesia care. This is accomplished by evaluating available evidence and providing recommendations for patient assessment, monitoring, and management with the goal of optimizing patient safety. It is expected that each recommendation will be individualized according to the needs of each patient.

C. Focus
These guidelines focus on the perioperative management of patients with the goal of improving postanesthetic quality of life, reducing postoperative adverse events, providing a uniform assessment of recovery, and streamlining postoperative care and discharge criteria. These Guidelines apply to patients of all ages who have received general anesthesia, regional anesthesia, or moderate or deep sedation. The Guidelines may need to be modified to meet the needs of certain patient populations, such as children or the elderly. The Guidelines do not apply to patients receiving inhalation local anesthesia without sedation, patients receiving minimal sedation, or patients receiving general anesthesia in the context of a direct laryngoscopy and bronchoscopy.
CAH Hospitals

- Current CAH manual is dated August 30, 2013
- Anesthesia standard starts at tag C-0322 and see 323
  - Most of the sections are the same
- The PPS hospital anesthesia standards provide more detailed information on how this section will be surveyed
  - Will cover the differences for CAH hospitals
- Much shorter section
  - Does not mention CRNA going to OB unit to put in epidural but most likely is treated the same

Anesthesia Standard CAH

C-0322

§485.639(b) Standard: Anesthetic Risk and Evaluation

(1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

Interpretive Guidelines §485.639(b)

The pre-anesthesia evaluation must be performed prior to inpatient or outpatient surgery. The pre-anesthesia evaluation must be performed by an individual qualified to administer anesthesia. The pre-operative anesthetic evaluation should include:

- Notation of anesthesia risk
CAH Pre-anesthesia Assessment  C-322

- Must be done by qualified practitioner
  - Example would include CRNA and anesthesiologist
- Includes what must be in the preanesthesia assessment
  - Notation of anesthesia risk
  - Anesthesia, drug and allergy history
  - Any potential anesthesia problems identified
  - Patient's condition prior to induction of anesthesia

Post Anesthesia Assessment CAH  322

- Cardiopulmonary status
- Level of consciousness
- Any follow-up care and/or observations and
- Any complications occurring during post-anesthesia recovery
- States that the post-anesthesia follow up report must be written prior to discharge from anesthesia services
  - This is different for other hospitals that have 48 hours
The End

Questions?

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TJC standards follow
ASGE, ACEP (ED), ENA
CMS HOSPITAL CONDITIONS OF PARTICIPATION (COPS) 2014

Surgery, PACU and Anesthesia Standards

CMS Hospital CoPs Section on PACU
### PACU 957  2014

- **Standard:** Must be adequate provisions for immediate post-op care
- Must be in accordance with acceptable standards of care, for all patients including same day surgery patients
  - Such as following the ASPAN standards of care and practice
- Separate room with limited access
- P&P specify transfer requirements to and from PACU

### PACU 957  2014  Advanced Notice of Changes

- CMS has published a memo published March 14, 2014 with advanced notice of changes
  - Includes some changes to the PACU standards
- Emphasizes need for post-operative monitoring of patients receiving IV opioids
  - Amends also nursing tag numbers 405, 409, and 412
- Want to be sure all patients on opioids, including PCA, are monitored carefully
- P&P required which includes how often patient has to be monitored, training of staff, equipment etc.
2014 Changes to PACU Section

### CMS Manual System

**Pub. 100-07 State Operations Provider Certification**

**TRANSMITTAL (Advance Copy)**

**Date:** 4/28/2014

**SUBJECT:** Revised Appendix A, Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for various provisions of 42 CFR 482.23(c), concerning medication administration, and 42 CFR 482.51(b)(4), concerning post-operative patient care.

NEW/REVISED MATERIAL - EFFECTIVE DATE: Upon Issuance

IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new-revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)

(If REVISED, N = NEW, D = DELETED) - (Only One Per Row)

<table>
<thead>
<tr>
<th>R/N/D</th>
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<td>R</td>
<td>Appendix A/ A-0405, §482.23(c) Standard: Preparation and Administration of Drugs: §482.23(c)(1)(v), (c)(1)(v)(b), &amp; (c)(2).</td>
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<td>Appendix A/ A-0557, §482.51(b) Standard: Delivery of Services/Immediate Post-operative Care: §482.51(b)(4).</td>
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**Center for Clinical Standards and Quality/Survey & Certification Group**

**DATE:** March 14, 2014

**TO:** State Survey Agency Directors

**FROM:** Director Survey and Certification Group

**SUBJECT:** Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-Operative Care of Patients Receiving IV Opioids

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**Memorandum Summary**

- **Medication Administration:** We are updating our guidance for the hospital medication administration requirements to:
  - Make clear that the medication administration requirements under the nursing services condition of participation (CoP) are related to only some components of the overall hospital medication process, but that hospitals are expected, through this and the related requirements under the pharmaceutical services and quality assessment/performance improvement CoPs, to take a comprehensive approach to the medication process.
  - Update our guidance for IV medications and blood transfusions in general; and
  - Reflect the need for patient risk assessment and appropriate monitoring during and after medication administration, particularly for post-operative patients receiving IV opioid medications, in order to prevent adverse events.

- **Immediate Post-operative Care:** Clarification is also being made to the guidance for the surgical services CoP requirement for hospitals to have adequate provisions for immediate post-operative care, to emphasize the need for post-operative monitoring of patients.
A-0957
(Rev.)

§482.51(b)(4). There must be adequate provisions for immediate post-operative care.

Interpretive Guidelines §482.51(b)(4)

Adequate provisions for immediate post-operative care means:

- Post-operative care must be provided to all surgical patients, including same-day surgery patients, in accordance with acceptable standards of practice.

- A post-operative care area, usually referred to as the post-anesthesia care unit (PACU), is a separate area of the hospital. Access is limited to authorized personnel.

- Policies and procedures specify transfer requirements to and from the PACU. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the PACU includes, but is not limited to:
  - Level of activity;
  - Respirations;
  - Blood pressure;
  - Level of consciousness;
  - Level of pain;
  - Patient color; and

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PACU 957        2014

- PACU assessment includes level of activity, level of pain, respiration, BP, LOC, patient color, Aldrete
- If not sent to PACU then close observation of patient until has gained consciousness by a qualified RN
- Surveyor is instructed to observe care provided in the PACU to make sure they are monitored and assessed prior to transfer or discharge
- Will look to determine if hospital has system to monitor needs of post-op patient transferred from PACU to other areas of the hospital
Post-Operative Monitoring 2014

- Hospitals are expected to have P&P on the minimum scope and frequency of monitoring in post-PACU setting
- Must be consistent with the standard of care
- Concerned about post-op patients receiving opioids
- Concern about risk for over-sedation and respiratory depression
- Once out of PACU not monitored as frequently
- Need appropriate assessment to prevent these complications (See Tag 405)
Perianesthesia Nursing Standards

2012-2014 Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements

www.aspan.org/Clinical-Practice/ASPAN-Standards

ASPAN Position Statements

www.aspan.org/Clinical-Practice/Position-Statements